(12) UK Patent Application (19) GB (11) 2 259 464 (13) A

(43) Date of A publication 17.03.1993

(21) Application No 9119370.6

(22) Date of filing 11.09.1991

(71) Applicant
Robinson & Sons Limited

(Incorporated in the United Kingdom)

Wheat Bridge, Chesterfield, Derbyshire, S40 1YE, United Kingdom

(72) Inventor
Richard Duncan Bradbury Robinson

(74) Agent and/or Address for Service
A A Thornton & Co
Northumberland House, 303-306 High Holborn, London, WC1V 7LE, United Kingdom

(51) INT CL[5]
A61L 15/58, C09J 7/02

(52) UK CL (Edition L)
B2E EM E1739 E402T E463T E466T E473S E551S E600T
U1S S1049 S1368

(56) Documents cited
GB 1548678 A GB 1285531 A EP0164319 A2
EP 0092999 A2

(58) Field of search
UK CL (Edition K) A5R, B2E EM
INT CL[5] A61L, C09J
Online databases: WPI

(54) Hydrocolloid dressing

(57) A dressing comprises a closed cell polymer foam layer having on one side of the foam layer an elastomeric adhesive composition comprising a hydrocolloid material and a water insoluble elastomeric binder, and may also include superabsorbent polymers.

GB 2 259 464 A

HYDROCOLLOID DRESSING

This invention relates to a bandage or dressing comprising a water impervious polymer foam on one side of the dressing and an adhesive composition on the other side. The adhesive composition comprises a mixture of a water swellable hydrocolloid and water insoluble elastomeric binders, and may also include superabsorbent polymers.

A hydrocolloid is a microgranular composition of natural material or synthetic polymers the granules being in a semi-hydrated state and hydrophilic, and being capable of absorbing many times their own weight of water to form a gel.

United States patent number 3339546 discloses the use of a dressing comprising a polyethylene film laminated with a bonding composition. The bonding composition comprises a mixture of a water-soluble or swellable hydrocolloid and an insoluble viscous gum-like elastic binder.

United States patents 3665918 and 3972238 disclose the use of a semi-open cell foamed polymer sheet. In particular, US-3972328 discloses a bandage comprising a

pressure-sensitive adhesive layer, a layer of semi-open cell flexible polymeric foam attached to the adhesive layer, and a water-impervious flexible polymeric film attached to the opposite side of the foam layer. The adhesive layer comprises rubbery elastomer having dispersed in it a water-soluble or swellable hydrocolloid or mixture of hydrocolloids, tackifier, and plasticiser.

The present invention uses a closed cell foam, rather than the semi-open cell foams used in the above described patents and in commercially available hydrocolloid dressings. The preferred foam is impermeable to water and water vapour and to bacteria. In conjunction with the water swellable hydrocolloid, the preferred foam has a low permeability to oxygen. It has been found in early stages of wound regeneration that foam impermeable to oxygen promotes angiogenesis (growth of blood vessels) into the wound area.

According to the present invention there is provided a dressing comprising closed cell polymer foam layer having on one side of said foam layer an elastomeric adhesive composition, the adhesive composition comprising a hydrocolloid material and a water insoluble elastomeric binder.

The term "closed cell polymer foam" as used herein means a foam in which the percentage of closed cells in the foam is higher than 70 percent. Preferably, the percentage of closed cells is substantially higher than 70 percent.

The preferred foam of the present invention is a polyethylene foam. Foamed polyethylene has been used in packaging applications, but it has not previously been considered for use as the impermeable layer for a hydrocolloid dressing. Furthermore, not all foamed polyethylene is suitable for such a dressing, since certain foams do not withstand the preferred sterilization by gamma or electron beam irradiation.

In a preferred embodiment of the invention the foam has from 165 to 250 cells per 25mm, with a most preferred level of 200 cells per 25mm. Foam ALVEO Grade TEE.0500/5 meets these requirements. This foam also has good insulation properties compared with other foams, having a thermal conductivity of about 0.052w/mK at 10°C. This foam is available in a flesh coloured (pink) version, if preferred to the standard white colour.

The preferred elastomeric binder is polyisobutylene (PIB), which preferably comprises from 15 percent to 30 percent by weight of the adhesive composition, the most preferred weight being 20 percent. A suitable grade of PIB is supplied by Exxon Chemicals as Vistanex LMNH, the molecular weight of which is 50000 (Flory). One advantage of this molecular weight is that it allows the adhesive composition to be cold compounded and reduces the risk of degradation on heating.

A further advantage is that this grade of PIB does not darken on heating and processing. Another major advantage of the LMNH grades is their resistance to irradiation by gamma rays and electron beams, which are preferentially used in order to sterilise the dressing.

The current commercially available hydrocolloid formulations show reduced flexibility and absorbency after irradiation, whereas the LMNH grades are much less affected, and retain a greater degree of flexibility.

A further advantage of the LMNH grades of PIB is that when compounded with the other ingredients described below, the resultant adhesive composition does not exhibit "cold flow" properties. Thus, the components of the adhesive do not ooze out of the edges of the dressing to anything like the same degree as occurs with other commercially available dressings over several months in storage.

A further, preferred component of the elastomeric

composition is liquid isoprene rubber (LIR). Heretofore, it was thought necessary to include tackifiers for use with PIB (see, for example, US 4147831, GB2089351 and EP130061). The inclusion of LIR, however, obviates the use of tackifiers and gives a high initial tack (green tack) and leaves no deposit on the skin. Its inclusion also enables the viscosity of the adhesive mass to be controlled and enables cold compounding to take place. The resulting adhesive composition is more elastic than previously known dressings and does not restrict articulation of joints near the wound area.

The adhesive composition preferably contains from 15 percent to 30 percent by weight of LIR with a most preferred level of 20 percent. A suitable grade of LIR has been found to be LIR50 obtained via Sieber Hegner Ltd, from Kuraray, Isoprene Chemicals Company Limited, Tokyo. The molecular weight is typically 47,000 (Flory).

Another advantage of this grade of LIR is that again it does not discolour on processing, since no heat has to be applied. It is also a hypoallergenic grade so that very few individuals show an allergic reaction compared with the frequently used Zinc Oxide and other adhesives. Again, it maintains its high tack after irradiation which is a significant advantage. In addition, it allows the elimination of the "keying layer" used in a number of previously known dressings to bond the hydrocolloid layer to the polyurethane foam/film layer. The LIR also contributes to the greater conformability of the finished dressing compared with other hydrocolloid dressings.

The hydrocolloid material preferably comprises one of the following components:-

CMC (carboxy methyl cellulose)
SCMC (sodium carboxy methyl cellulose)
HPMC (hydroxy propyl methyl cellulose)

Although the use of Sodium CMC is disclosed in US-4204540, US-4166051 and EP-107526, it has been found that the choice of CMC type and granule size affects performance.

It has been found that control of particle size is important in processing to achieve uniform blending of the ingredients. If a particle size is of greater than 212 microns, gel blocking takes place, whereby the outside of a granule swells on absorbing blood or exudate, which then prevents the fluid penetrating the inside of the granule. If the particle size is less than 125 microns, then the particles are dusty and do not flow as well from the storage hoppers etc. In addition, the dust can cause breathing/irritation problems for the plant operatives.

Thus, the range of particle sizes is preferably from 150 to 212 microns with a most preferred particle size of 150 microns.

Both SCMC and HCMC appear to have good resistance to degradation by irradiation, as already described, so that the finished dressing does not significantly lose absorbency after gamma or electron beam irradiation.

One SCMC grade that meets the above requirements for particle size and resistance to irradiation has been found to be Walocel C. Sodium 15000 PPA from Wolff Walsrode - a Bayer subsidiary.

An alternative HPMC grade from Courtaulds - Celacol 450 - has similar properties and performs satisfactorily. CMC, SCMC or HPMC may be incorporated in the adhesive composition at levels of between 30 percent and 65 percent of the weight when used without super absorbent polymers (SAP). When used with 10 percent of SAP, the level of CMC, SCMC or HPMC is preferably 40 percent to 50 percent.

In order to improve the absorbency characteristics of the dressing still further, super absorbent polymers (SAP) may be incorporated along with the CMC, SCMC or HPMC. Typically, a SAP will absorb 60 -80 times its own weight of a saline fluid such as a wound exudate, compared with 10 - 20 times its own weight for a SCMC or an absorbent cotton wool. The use of a starch acrylonitrile graft copolymer - an early SAP - is mentioned in US Patent numbers 4192785, 4204540 and 4253460. However, these SAP's have been criticised for the presence of low percentages of acrylonitrile monomer, which have potentially toxic side effects.

The preferred super absorbent polymer included in our invention is DP355 produced by Courtauld Chemicals. This particular grade has been chosen because:-

(a) of its high purity in manufacture and very low level of residual monomer, having passed safety tests at Huntington Research Laboratory.

(b) careful control of particle size, ie: no greater than 212 microns, and not less than 125 microns; if larger particles are used, then "gel blocking" occurs - as described above.

(c) specific resistance to cleavage of the molecular chains on gamma or electron beam irradiation, which cleavage seems to take place with other grades of polysaccharide absorbent materials.

The SAP's may be included at between 5 percent and 20 percent - the most preferred range being 10 percent to 15 percent, by weight of the adhesive composition.

Much improved absorbencies have been recorded in

laboratory tests comparing the absorbency of a commercially available dressing at 44 gms/100cm^2 to 86 gms/100cm^2 for the hydrocolloid dressing of the present invention. When the area weight of the hydrocolloid mix of the dressing was taken into account, the absorbency figure was increased from 3.63 to 5.82 gms/gm, ie: an increase of 60 percent compared with the tested, commercially available dressing.

CLAIMS

1. A dressing comprising a closed cell polymer foam layer having on one side of said foam layer an elastomeric adhesive composition comprising a hydrocolloid material and a water insoluble elastomeric binder.

2. A dressing according to claim 1, wherein said adhesive composition includes polyisobutylene.

3. A dressing according to claim 2, wherein the polyisobutylene comprises from 15 percent to 30 percent by weight of the adhesive composition.

4. A dressing according to any preceding claim, wherein the adhesive composition additionally comprises liquid isoprene rubber.

5. A dressing according to claim 4, wherein the adhesive composition contains from 15 percent to 30 percent by weight of liquid isoprene rubber.

6. A dressing according to any preceding claim, wherein said hydrocolloid material comprises a methyl cellulose.

7. A dressing according to claim 6, wherein the methyl cellulose comprises carboxy methyl cellulose, sodium carboxy methyl cellulose, or hydroxy propyl methyl cellulose.

8. A dressing according to claim 6 or claim 7, wherein the methyl cellulose comprises from 30 percent to 65 percent by weight of the adhesive composition.

9. A dressing according to any preceding claim, wherein the adhesive composition additionally comprises a super-absorbent polymer.

10. A dressing according to claim 9, wherein the super-absorbent polymer comprises from 5 percent to 20 percent by weight of the adhesive composition.

11. A dressing according to any preceding claim, wherein said polymer foam is a polyethylene foam.

12. A dressing according to any preceding claim, wherein the polymer foam is substantially impermeable to water and water vapour.

13. A dressing according to any preceding claim, wherein the dressing is substantially impermeable to oxygen.

14. A dressing substantially as hereinbefore described.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number

GB 9119370.6

Relevant Technical fields

(i) UK Cl (Edition K) B2E (EM) A5R

(ii) Int Cl (Edition 5) A61L C09J

Search Examiner

V V BAILEY-WOOD

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Date of Search

30 SEPTEMBER 1992

Documents considered relevant following a search in respect of claims 1-14

Category (see over)	Identity of document and relevant passages		Relevant to claim(s)
Y	GB 1548678	(SQUIBB)	All
Y	GB 1285531	(JOHNSON AND JOHNSON)	All
Y	EP A2 0164319	(COLOPLAST) see page 4 lines 13-14	All
Y	EP A2 0092999	(SQIBB)	All

Category	Identity of document and relevant passages	Relevant to claim(s.

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

Published 1993 at The Patent Office, Concept House, Cardiff Road, Newport, Gwent NP9 1RH. Further copies may be obtained from Sales Branch, Unit 6, Nine Mile Point, Cwmfelinfach, Cross Keys, Newport, NP1 7HZ. Printed by Multiplex techniques ltd, St Mary Cray, Kent.